



WHOLESALE



MARKETERS



ASSOCIATION

April 2, 2003

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Dockets Management Branch (HFA-305) Food and Drug Administration 5600 Fishers Lane, Room 1601 Rockville, Maryland 20852

Re:

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Docket No. 02N-0278 -- Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Proposed Regulation Published February 3, 2003, 68 Federal Register 5428)

Dear Sirs:

These comments are submitted by the American Wholesale Marketers Association ("AWMA"), the only international trade association working on behalf of convenience distributors in the United States. Our distributor members represent more than \$45 billion in U.S. convenience product sales annually. Associate members include manufacturers, brokers, retailers and others allied to the convenience product industry. Our comments focus on the impact of the proposed regulations on AWMA's distributor member companies.

The AWMA recognizes the need to safeguard food security, and our industry is committed to promoting the safety of our food supply to ensure the health and well-being of all Americans. The proposed regulations reflect the efforts by the agency to consider industry issues and concerns that were raised in informal comments last year. AWMA commends FDA for this initiative, and we have only a few additional comments. Unless otherwise indicated, references are to the sections of the proposed amendments to Title 21, Code of Federal Regulations.

Although very few AWMA distributor members are direct food importers who would be obligated to comply with these proposed regulations, many of our members are the initial customers of the importers. As such, our members would be directly affected by any new requirements which interrupt the customary flow of imported food products. Our overall concern is that compliance with the formalities of the prior notice requirements could take precedence over the purpose of the statute and regulations, i.e., to provide FDA with time to stop a shipment of food that poses a serious threat.

In particular, proposed Sec. 1.278(a) would provide that any omission or inaccuracy in a prior notice will cause the subject shipment to be held at the port of entry until the notice is corrected. No exceptions to this result are indicated. This proposed rule ignores the flexibility that Congress granted FDA in the new Section 801(m) of the Food, Drug, and Cosmetic Act (21 USC Sec. 381(m)). Specifically, clause 381(m)(2)(B)(ii) directs FDA to "determine whether there is in the possession of the [agency] any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals." We submit that there will be many instances in which a prior notice will contain incomplete or inaccurate information, but, nevertheless, that does not constitute "credible"

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evidence" that the shipment represents a "serious threat." 21 CFR Sec. 1.278 should include a waiver or other escape mechanism to allow agency officials to release evidently safe food products even if the electronic "paperwork" is not complete.

We recommend that the agency also develop guidance documents for the import inspectors, whether they be FDA or Customs officials. These guidance documents would identify foreign shippers, manufacturers, growers, etc., whose shipments do or do not prompt questions about the potential threat. Perhaps the principal criterion would be the country of origin because of disease or sanitation problems in the past. Perhaps the focus should be shipments from shippers on which the agency has little or no history. We cannot presume to know what criteria will provide the most effective protection, but there must be some criteria. Otherwise, we envision a situation in which the formalities of documentation could obscure the detection of the more serious threats.

International trade is cost-effective only when it is fast and flexible. Absolute food security would bring food imports to a standstill, so there must be a balance between security and efficient trade. We are concerned that the balance struck in these proposed rules goes too far toward security, and the proposal ignores the flexibility granted by Congress.

Thank you for the opportunity to present our views.

Respectfully submitted,

Scott Ramminger, President

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American Wholesale Marketer Association